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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,146	11/17/2000	Christopher T. Boyle	6006-018	6734

7590 07/16/2004

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EXAMINER

MILLER, CHERYL L

ART UNIT PAPER NUMBER

3738

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/716,146	Applicant(s) BOYLE, CHRISTOPHER T.	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 20 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 20, and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to the rejection of claims 16 and 26-28 over the Ragheb et al. reference (US 6,096,070) have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to the rejection of claims 16, 20, and 26-28 over the Brown et al. reference (US 6,071,305) have been considered and in view of the amendment are found non-persuasive. Applicant has again argued that Brown does not anticipate structural elements having separate layers, specifically, that Brown does not disclose a void layer between two layers, and argues further that Brown fails to disclose a first region having a base layer and a second region having a second layer covering the base layer, the second region further comprising a layer of void space intermediate the base and second layers and enclosed therebetween. The examiner disagrees. The examiner's position is believed to be adequately described in the previous office action, however will be elaborated for further clarity. Brown has disclosed two different embodiments having the layers claimed. One embodiment is shown in figures 1-10. Cross-sectional views of Brown's structural elements are shown in figures 3-10. Brown discloses the cross-section of structural elements of this embodiment to be shapes other than circular, such as square or rectangle (col.5 line 65-col.6 line 5). When using Brown's disclosed square or rectangular cross-section, the structural elements have two layers, a top layer and bottom layer, and sidewalls of the square cross-section enclose the void space (20, which also will also be square/rectangular) between the top and bottom layers. A second embodiment is shown in figure 12. Brown has shown in figure 12, a cross-section of a structural element,

having a base layer, second layer covering the base layer, and a void layer therebetween (void layer being the channel where 23 and 44 occupy, and which layer extends like a channel along the structural element, col.11, lines 55-58). Therefore, Brown does indeed disclose the endoluminal stent that is claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16, 20, and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al. (US 6,071,305, cited in previous office action). Referring to claim 16, Brown discloses an endoluminal stent (11, 40'') comprising a plurality of structural elements (element 12 seen in figure 1, however having the structure, mesh or roving wire stents, each elongated member 12 being a filament or fiber which forms a mesh stent, disclosed in col.7, lines 34-40, that is, although Brown has shown a helical stent made of one structural element in fig.1, Brown also discloses use of a stent with multiple structural elements, wires/fibers/filaments, col.7, lines 34-40; or element seen in cross section fig.12 and disclosed in col.11, lines 50-61) forming a radially expandable cylindrical member, the structural elements are fabricated from metal (col.7, lines 12-19) having a wall thickness (thickness of wire/fiber/filaments, shown in fig.5-9 and 12), wherein the structural elements (member 12, or member shown in fig.12) are comprised of a first region comprising a base layer (layer on inside of vessel as seen in cross section, for example fig.

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6 or 8, and using Brown's disclosed square cross-section, one side of the square is the base layer; and bottom layer of 40'' in fig.12) and a second region comprising a second layer (layer touching vessel as seen in cross section, for example fig. 6 or 8, and using Brown's disclosed square cross-section, the opposing side is the second layer; and top layer of 40'' seen in fig.12) covering the base layer, the second region further comprising a layer of void space (cavity 20 in fig.1-10; and channel occupied by 23 in fig.12) intermediate the base and second layers and enclosed therebetween (as seen in cross section, for example fig. 6 or 8, and using Brown's disclosed square cross-section, the void space 20 is enclosed by the side walls of the square; and channel occupied by 23 is enclosed by walls seen in fig.12) and a plurality of pores (pores may be openings 22, 28, 54; col.6, lines 12-21 or alternatively pores may be pores in the porous stent material col.10, lines 36-38) passing through at least one of the base and second layers and communicating with the void space (20 or channel) and at least one bioactive agent (23) retained within the void space (20 or channel) and elutable through the plurality of pores (22, 28, 54).

Referring to claim 20, Brown discloses a degradable plug (matrix 27 extending into pore, or membrane 34, 50; col.8, lines 62-65; col.9, lines 12-21) residing within the plurality of pores.

Referring to claim 26, Brown discloses a stent (10, 40'') having structural elements (member 12 in fig.1-10 or member shown in fig.12) comprising a material selected from the group claimed (col.7, lines 12-19).

Referring to claim 27, Brown discloses a bioactive or active agent (23) selected from the group claimed (col.5, lines 1-27).

Referring to claim 28, Brown discloses a void space (20 or channel in fig.12) comprising a plurality of independent internal cavities along the length of the structural elements (cavity 20 may be intermittent, col.5, lines 52-55).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER